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09/636,185	08/10/2000	John F. Gerber	GER-100XC1	6539

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/03/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/636,125

Applicant(s)

Gerber et al.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 11, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 9-11, 28, and 31 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 9-11, 28, and 31 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6) ☐ Other:

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### **DETAILED ACTION**

Claims 1, 5, 9-11, 28 and 31 are pending in the application and were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: Claim 1 recites 'wherein said microorganism is found in association with nematode'. This phrase is grammatically awkward. Judging from claim 1 prior to the amendment, it is thought that Applicants intend for this to read '...in association with nematodes'. This is a minor typographical error. Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

New Claim 31 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing *Pasteuria* endospores with a microorganism which is identified by ATCC PTA-2324 (the deposited species), does not reasonably provide enablement for the growth of *Pasteuria* via administration of any microorganism which hybridizes to SEQ ID No. 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants' arguments with regard to the rejection of claims 1, 4, 7 and 9-11 (which previously stated 'wherein said microorganism has DNA that hybridizes with SEQ ID No. 1 under moderate to high stringency conditions') was fully considered, but not found persuasive.

Applicants stress that culturing of *Pasteuria* in the past has been extremely difficult, and recite a long-standing need for an in-vivo process for producing *Pasteuria* endospores (p.3-Arguments). Applicants principally argue that it would not take undue experimentation to ascertain which bacterial species, besides the microorganism

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deposited as ATCC PTA-2324 would facilitate the growth of *Pasteuria in-vitro*.

Applicants contend that hybridization techniques are well known, and the DNA of the microbes can be easily tested to determine if they hybridize to SEQ ID NO.1 (p.5-Arguments). Applicants further state that claim 1 recites 'in association with nematodes', thereby expressing that a search for the particular bacteria which hybridize with SEQ. ID. No. 1 would not involve undue experimentation (p.4-Arguments).

It is not argued that it would be undue experimentation to ascertain what microorganism would hybridize to SEQ ID NO. 1. It was made clear in the previous Office Action that many, perhaps thousands of bacteria would potentially hybridize to SEQ ID No. 1 because SEQ ID NO. 1 is portion of DNA which is conserved in many bacteria, especially *E.coli*. What would involve undue experimentation is determination of the particular bacteria which actually helps *Pasteuria* to grow. As evidenced by Applicants arguments, most attempts to grow *Pasteuria in-vivo* have been a failure. Applicants have not shown that every bacteria which could potentially hybridize to SEQ ID No. 1 would actually prove beneficial toward *Pasteuria* growth. Consequently, in light of the difficulty of growing *Pasteuria in-vitro*, the skilled artisan would not have an expectation that bacteria such as *E.coli* (which would hybridize to SEQ ID No. 1) would promote *Pasteuria* growth.

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Further, the term 'in association with nematodes' is quite broad. It is noted that terms in a claim are read in light of the Specification, but given their broadest interpretation upon examination for enablement purposes. Any bacteria could potentially be 'in association' with nematodes since nematodes routinely infect plant root stocks. These root stocks contain bacteria which nematodes come into 'association with'. It is further noted that it would be unpredictable to ascertain whether every nematode will actually provide the microorganism which has been categorized as ATCC PTA-2324. In any event, Applicants have provided information regarding a specific bacteria which promotes the growth of *Pasteuria* in-vivo, a method which has, in the past, been difficult to accomplish. However, the skilled artisan would not expect that any microorganism which would hybridize to SEQ ID No. 1 would provide for the results as shown in the Instant specification with regard to the microorganism classified as ATCC PTA-2324.

*In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; **however, he must not be permitted to achieve this dominance by claims which are**

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***insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art***, in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (Emphasis added)

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Moriama et al. (JP 06165670A).

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Moriama et al. (JP 06165670A) disclosed a method for producing *Pasteuria penetrans* via culturing with crushed nematodes (English Abstract).

The phrase 'wherein said microorganism is found in association with nematode[s]' was given it's broadest interpretation within reason. The Specification teaches that the microorganism is indigenous to the nematode, and is thereby released upon crushing the nematode body (p.6 Instant specification). Because Moriama et al. performed the same method via crushing the nematode body, and subsequently culturing the *P. penetrans* in this medium, it is deemed that Moriama et al. also released the 'microorganism' which was inherently indigenous to the nematode. Moriama et al. did not specifically mention where the culture was mixed or antibiotics were added (claims 9 and 10). Because the method is the same, it is deemed that the *Pasteuria* spores would also be the same absent convincing evidence to the contrary (claim 28).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter



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sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moriama et al. (JP 06165670A) in view of ATTC (1992).

The teachings of Moriama et al. (JP 06165670A) were discussed supra. Moriama et al. did not specifically teach wherein lipids and or manganese sulfate were added to support the growth of *Pasteuria* endospores.

ATTC (1992) reported several media formulations which included magnesium sulfate as a nutritive addition for Bacterial growth (i.e., pp.478-479, formulations 1479, 1483, 1486, 1492).

One of ordinary skill in the art would have been motivated to have added magnesium sulfate into a culture medium for bacteria because addition of magnesium sulfate would have provided extra nutrition to facilitate the growth process of said bacteria. It was clear from the ATTC catalog that magnesium sulfate was a common additive into bacterial culture media. Thus, the ordinary artisan would have had a reasonable expectation that the addition of magnesium

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sulfate would have been an advantageous addition to a growing bacterial culture to ensure proper bacterial nutrition for growth.

***Allowable Subject Matter***

Claim 5 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

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MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
CHRISTOPHER H. TATE  
PRIMARY EXAMINER